UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

MEMORANDUM

Date: January 9, 2014

Subject: Fludioxonil. Occupational and Residential Exposure Assessment for Proposed Uses on Post-Harvest Pome Fruit.

PC Code: 071503	**DP Barcode**: D412253
Decision Nos.: 475789	**Registration No.**: 100-RLNL-Scholar EZ
Petition Nos.: NA	**Regulatory Action**: Section 3
Risk Assessment Type: Single Chemical	**Case No.**: 7017
TXR No.: N/A	**CAS No.**: 131341-86-1
MRID No.: N/A	**40 CFR**: §180.516

FROM: Lata Venkateshwara, Environmental Scientist
Health Effects Division/Risk Assessment Branch 1 (7509P)

THRU: Zaida Figueroa, ExpoSAC Designated Reviewer
Cassi Walls, ExpoSAC Designated Reviewer
Exposure Science Advisory Council

Kelly Lowe, Environmental Scientist
Charles Smith, Branch Chief
Health Effects Division/Risk Assessment Branch 1 (7509P)

TO: William Cutchin, RM20
Registration Division/Fungicide Branch (7505P)

The Registration Division (RD) requested that the Health Effects Division (HED) conduct an exposure and risk assessment for the new proposed uses of fludioxonil on post-harvest pome fruit. The formulated end-use product evaluated in this assessment is Scholar®EZ (EPA Reg. # 100-RLNL-Scholar EZ; containing 98% fludioxonil). This product is a powder intended for use with a thermal fogger machine. This memorandum serves as HED's assessment of occupational and residential exposure and risk from the proposed use of fludioxonil.

It is HED policy to use the best available data to assess exposure. Several sources of generic data were used in this assessment as surrogate data in the absence of chemical-specific data, including the Pesticide Handlers Exposure Database Version 1.1 (PHED 1.1); the Agricultural

Handler Exposure Task Force (AHETF) database; the Outdoor Residential Exposure Task Force (ORETF) database; and the Residential SOPs (indoor environments). Some of these data are proprietary, and subject to the data protection provisions of the *Federal Insecticide, Fungicide, and Rodenticide Act* (FIFRA).

Note: This memorandum was reviewed by the Exposure Science Advisory Committee (ExpoSAC) on December 5, 2013.

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1.0 Executive Summary

This document presents an occupational and residential exposure/risk assessment for the proposed application of fludioxonil to post-harvest pome fruit treatment by thermal fogging. The proposed uses are anticipated to result in occupational exposure, but not residential exposure. There are currently registered residential uses that have been summarized in this document.

Proposed Use Profile:
In the current action, the registrant, Syngenta Crop Protection, LLC, proposes a new pesticide registration of Scholar® EZ, an end-use product containing 98% fludioxonil, for post-harvest use on pome fruit to reduce damage from blue and gray mold, Bull's-eye rot, Rhizopus rot, Bitter rot, Sphaeropsis rot, Phacidiopycnis rot, Speck rot, White rot and Alternaria rot. The proposed label states that Scholar® EZ is a powder intended for use with a thermal fogger machine. The proposed application rate is 3.6 ounces of product, or 0.2205 pounds of fludioxonil, per 90,000 lb of fruit. The label states to apply to fruit within 24 hours to harvest and prior to placing in storage for maximum decay control.

Exposure Profile
There is a potential for short- and intermediate-term occupational exposure to fludioxonil during mixing, loading, and other handling tasks; and for short- and intermediate-term occupational exposure during post-application activities. Chronic exposure is not expected for the proposed use patterns associated with fludioxonil.

The proposed label Scholar® EZ directs handlers (including mixers, loaders, persons cleaning or setting up the fogging equipment and persons handling treated fruit) to wear long sleeved shirt and long pants, chemical resistant gloves, shoes and socks, and protective eyewear (such as goggles, safety glasses or a face shield). The label states that fumigating applicators must wear full-face respirator with organic vapor filter.

Hazard Concerns:
Fludioxonil is of low acute toxicity, since technical fludioxonil is in Toxicity Category III or IV for the full battery of acute tests and is not a dermal sensitizer. No short-or intermediate-term dermal point of departure (POD) was selected for fludioxonil. The point of departure (POD) for the short- and intermediate-term incidental oral and inhalation endpoints in residential and occupational settings is based upon the NOAEL of 50 mg/kg/day in the subchronic dog study. At the LOAEL of 250 mg/kg/day, there were decreased absolute body weights in both sexes, diarrhea, hematological alterations (increased platelets and fibrin, decreased red cells, hemoglobin, and packed cell volume), clinical chemistry alterations (increased alpha-1 and alpha-2 globulin in females), increased liver weights in both sexes, increased testes and ovary weights, and an increased severity (but not incidence) of bile duct proliferation. A body weight of 80 kilograms is used in both short- and intermediate-term inhalation assessments to represent the bodyweight of an average adult. Fludioxonil is classified as "not likely to be carcinogenic to humans;" therefore, a cancer assessment was not conducted.

HED's level of concern (LOC) for non-cancer risks (i.e., level of concern for MOEs or Margins of Exposure) is defined by the uncertainty factors. Both residential and occupational inhalation exposure scenarios will utilize a 10x uncertainty factor for human to human extrapolation (UF_H), a 10x for animal to human extrapolation (UF_A), and a 10x database uncertainty factor due to the lack of a required route-specific subchronic inhalation study for a total level of concern (LOC) of 1000. HED's Hazard and Science Policy Council (HASPOC) used a weight-of-evidence approach to require a 90-day inhalation study (Memo, D. Smegal, 29-FEB-12, TXR# 0050679).

Residential Exposure/Risk:

There are no new residential uses proposed for fludioxonil; however, fludioxonil is registered for use in residential areas, including parks, golf courses, athletic fields, residential lawns, ornamentals, and greenhouses. The residential uses were reassessed in a previous memo (Memo, D396573, 9/7/2012, L. Venkateshwara) to reflect updates to HED's Residential Standard Operating Procedures (SOPs), 2012 and have been updated here to reflect a new inhalation POD. Short-term inhalation risk estimates to residential handlers do not exceed HED's LOC for all scenarios (i.e., MOEs $\geq$ 1000). Post-application incidental oral risk estimates also do not exceed HED's LOC for any of the scenarios assessed (i.e., MOEs $\geq$ 100).

Occupational Handler Exposure:

Occupational handlers are anticipated to have short- and intermediate-term dermal and inhalation exposures. However, since no short- or intermediate-term dermal PODs were selected, only inhalation exposures are assessed. There are no short- and intermediate-term occupational risk estimates of concern associated with the proposed new use of fludioxonil (i.e., MOEs $\geq$ 1000).

Occupational Post-application Exposure:

Since no short- or intermediate-term dermal PODs were selected, post-application dermal exposures and risks were not quantitatively assessed for the proposed post-harvest uses on pome fruit. Post-application inhalation exposure is expected to be negligible since the proposed Scholar® EZ label requires that no entry into the treated room be allowed for 8 hours if there is no ventilation followed by one hour of mechanical ventilation, or for 24 hours with no ventilation.

Review of Human Research

This risk assessment relies in part on data from studies in which adult human subjects were intentionally exposed to a pesticide or other chemical. These data, which include studies from PHED 1.1; the AHETF database; and the ARTF database; are (1) subject to ethics review pursuant to 40 CFR 26, (2) have received that review, and (3) are compliant with applicable ethics requirements. For certain studies, the ethics review may have included review by the Human Studies Review Board. Descriptions of data sources, as well as guidance on their use, can be found at the Agency website[1].

[1] http://www.epa.gov/pesticides/science/handler-exposure-data.html and http://www.epa.gov/pesticides/science/post-app-exposure-data.html

2.0 Summary of Conclusions/Data Deficiencies

There are no short- and intermediate-term occupational risk estimates of concern associated with the proposed new use of fludioxonil. There are no data gaps in the exposure database.

3.0 Hazard Characterization

The toxicology database for fludioxonil is considered complete for risk assessment purposes. The acute toxicity and toxicological points of departure for occupational/residential exposure and risk assessment for fludioxonil are summarized in Tables 3.1 and 3.2, respectively. Fludioxonil has low acute toxicity – Toxicity Category IV for acute inhalation and acute oral toxicity and Category III for acute dermal toxicity. It is classified as Category III for primary eye irritation and Category IV for primary skin irritation. It is not a dermal sensitizer. The potential enhanced sensitivity of infants and children from exposure to fludioxonil, as required by the Food Quality Protection Act of 1996, was previously addressed by HED's FQPA Safety Factor Committee (6/13/2002), which concluded that the 10X safety factor could be removed (i.e., reduced to 1X). The inhalation endpoint has been reevaluated since the last assessment (Memo, L. Venkateshwara, January 13, 2013, D401448).

Table 3.1. Acute Toxicity of Technical Grade Fludioxonil.

Guideline No.	Study Type	MRID No.	Results	Toxicity Category
870.1100	Acute Oral	43124105	LD_{50} > 5000 mg/kg	IV
870.1200	Acute Dermal	43124106	LD_{50} > 2000 mg/kg	III
870.1300	Acute Inhalation	43080019	LC_{50} = 2.636 m/L	IV
870.2400	Primary Eye Irritation	43124107	slight irritant	III
870.2500	Primary Skin Irritation	43124108	non-irritating	IV
870.2600	Dermal Sensitization	43080024	not a sensitizer	-

Table 3.2. Summary of Toxicological Doses and Endpoints for Fludioxonil for Use in Occupational and Non-Occupational Human-Health Risk Assessments.

Exposure/ Scenario	POD	Uncertainty/ FQPA SFs	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Incidental Oral Short- (1-30 days) and Intermediate-Term (1-6 months)	NOAEL = 50 mg/kg/day	UF_A = 10X UF_H = 10X FQPA SF = 1X	Residential LOC for MOE = 100	Subchronic toxicity in dogs. LOAEL = 250 mg/kg/day based upon decreased absolute body weights in both sexes, diarrhea, hematological alterations (increased platelets and fibrin, decreased red cells, hemoglobin, and packed cell volume), clinical chemistry alterations (increased alpha-1 and alpha-2 globulin in females), increased liver weights in both sexes, increased testes and ovary weights, and an increased severity (but not incidence) of bile duct proliferation.

Table 3.2. Summary of Toxicological Doses and Endpoints for Fludioxonil for Use in Occupational and Non-Occupational Human-Health Risk Assessments.				
Exposure/ Scenario	POD	Uncertainty/ FQPA SFs	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Dermal Short- (1-30 days) and Intermediate-Term (1-6 months)	No hazard identified and therefore quantification is not required. There are no developmental concerns via the dermal route and no systemic toxicity was seen following dermal exposure.			
Inhalation Short- (1-30 days) and Intermediate-Term (1-6 months)	Oral NOAEL = 50 mg/kg/day (inhalation absorption = 100%)[a]	UF_A = 10X UF_H = 10X FQPA SF = 1X UF_{DB} = 10X	Residential / Occupational LOC for MOE = 1000	Subchronic toxicity in dogs. LOAEL = 250 mg/kg/day based upon decreased absolute body weights in both sexes, diarrhea, hematological alterations (increased platelets and fibrin, decreased red cells, hemoglobin, and packed cell volume), clinical chemistry alterations (increased alpha-1 and alpha-2 globulin in females), increased liver weights in both sexes, increased testes and ovary weights, and an increased severity (but not incidence) of bile duct proliferation.
Cancer (oral, dermal, inhalation)	Classification: Group D chemical - not classifiable as to human carcinogenicity.			

Point of departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no-observed adverse-effect level. LOAEL = lowest-observed adverse-effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_{DB} = to account for the absence of key date (i.e., lack of a critical study). FQPA SF = FQPA Safety Factor. PAD = population-adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern.

[a] Inhalation absorption default value of 100% is used with oral toxicity endpoint for route-to-route extrapolation.

4.0 Use Profile

Table 4.1 provides a summary of the proposed uses of fludioxonil.

Table 4.1. Summary of Proposed Uses for Fludioxonil.					
Crops	Treatment Type/Target of Application	Application Equipment	Maximum Application Rate[1]	Treatment Interval and Comments	Comments
Scholar® EZ (EPA Reg.# 100- RLNL-Scholar EZ)					
Pome Fruit[2]	Post-harvest fruit prior to placing in storage	Apply with thermal fogger machine (fogging into storage facility)	3.6 ounces or 0.2205 pounds of fludioxonil per 90,000 lb of fruit or 0.0000024 lb ai per lb of fruit	Apply within 24 hours of harvest.	Ensure proper distribution of the product on the fruit. Treat only dry fruit. For maximum decay control during storage, treat fruit once before storage.

[1] Rate = Maximum application rates specified on proposed labels.

[2] Pome fruit includes Apple (*Malus domestica*), Azarole (*Crataegus azarolus*), Crabapple (*Malus* spp.), Loquat (*Eribotrya japonica*), Mayhaw (*Crataegus aestivalis, C. opaca, and C. rufula*), Medlar (*Mespilus Germanic*), Pear (*Pyrus communis*), Pear, Asian (*Pyrus spp*), Quince (*Cydonia oblonga),Quince,Chinese (Chaeonomeles speciosa),* Quince, Japanese *(Chaenomeles japonica),* Tejocote *(Crataegus mexicana) and cultivars,* varieties, and/or hybrids of these.

5.0 Residential Exposure and Risk Estimates

There are no proposed residential uses at this time; however, fludioxonil is currently registered for use in residential areas, including parks, golf courses, athletic fields, residential lawns, and ornamentals. In a previous assessment (Memo, L. Venkateshwara, 9/7/12, D396573), HED reassessed the existing residential uses of fludioxonil using the 2012 Residential SOPs. These scenarios have been updated here to reflect a revised inhalation POD. Short-term inhalation risk estimates to residential handlers did not exceed HED's LOC for all scenarios (i.e., MOEs ≥ 1000). Post-application incidental oral risk estimates also did not exceed HED's LOC for any of the scenarios assessed (i.e., MOEs ≥ 100).

Table 5.1. Short-term Residential Handler Exposure and Risk Estimates for Fludioxonil.

Exposure Scenario	Application Rate[a]	Area Treated Daily[b]	Baseline Unit Exposures[b,c] (mg/lb ai)	Baseline Dose[d] (mg/kg/day)	Baseline MOE[e]
			Inhalation	Inhalation	Inhalation
Mixer/Loader/Applicator					
Mixing/Loading/Applying Wettable Powder in Water-soluble Packaging with Manually-pressurized Handwand to Turf[f]	0.0000156 lb ai/ ft^2	1000 ft^2	0.018	3.5E-06	14,000,000
Mixing/Loading/Applying Wettable Powder in Water-soluble Packaging with Backpack Sprayer to Turf[f]	0.0000156 lb ai/ ft^2	1000 ft^2	0.018	3.5E-06	14,000,000
Mixing/Loading/Applying Wettable Powder in Water-soluble Packaging with Hose- end sprayer to Turf	0.68 lb ai/A	0.5 acres	0.034	1.4E-04	350,000
Mixing/Loading/Applying Wettable Powder in Water-soluble Packaging with Sprinkler Can to Turf	0.0000156 lb ai/ ft^2	1000 ft^2	0.034	6.6E-06	7,500,000
Mixing/Loading/Applying Wettable Powder in Water-soluble Packaging with Manually-pressurized Handwand to Gardens and Trees	0.00094 lb ai/ft^2	1200 ft^2	0.018	0.00025	200,000
Mixing/Loading/Applying Wettable Powder in Water-soluble Packaging with Backpack Sprayer to Gardens and Trees	0.00094 lb ai/ft^2	1200 ft^2	0.018	0.00025	200,000
Mixing/Loading/Applying	0.00094 lb	1200 ft^2	0.034	0.00048	100,000

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Exposure Scenario	**Application Rate[a]**	**Area Treated Daily[b]**	**Baseline Unit Exposures[b,c] (mg/lb ai)**	**Baseline Dose[d] (mg/kg/day)**	**Baseline MOE[e]**
			Inhalation	**Inhalation**	**Inhalation**
Wettable Powder in Water-soluble Packaging with Hose- end sprayer to Gardens and Trees	ai/ft^2				
Mixing/Loading/Applying Wettable Powder in Water-soluble Packaging with Sprinkler Can to Gardens and Trees	0.00094 lb ai/ft^2	1200 ft^2	0.034	0.00048	100,000

a. Application rates based on label for fludioxonil (Medallion® Fungicide, EPA Reg# 100-769).
b. Based on HED's Standard Operating Procedures for Residential Pesticide Exposure Assessment; Lawns/Turf (February 2012).
c. Baseline Inhalation: no respirator.
d. Dose (mg/kg/day) = daily unit exposure (mg/lb ai) x application rate (lb ai/area treated or amount handled) x Area treated or Amount handled * absorption factor (inhalation = 100%) / body weight (80 kg).
e. MOE = NOAEL (50 mg/kg/day) / daily dose (mg/kg/day). Level of concern = 100.
f. The recommended amount handled for these equipment scenarios is in units of gallons/day in the HED Residential SOP (February 2012); however, the label does not provide an application rate in units of lbs ai/gallon. Therefore, 1000 ft^2 was assumed for the area treated, representing a worst-case broadcast spray.

Table 5.2 Short -Term Residential Post-application Exposure and Risk Estimates for Fludioxonil.				
Lifestage	Post-application Exposure Scenario		Dose (mg/kg/day)	**Short-term MOEs[4]**
Child 1 < 2 year old	Turf - sprays	Hand to Mouth[1]	0.0101	4,800
		Object to Mouth[2]	0.00031	160,000
		Incidental Soil Ingestion	2.2E-05	2,200,000

1. **Hand-to-Mouth** = [Hand residue loading (mg/cm^2)*(fraction hand surface area mouthed/event (0.127/event)*typical surface area of one hand (150 cm^2))*(exposure time (1.5 hrs/day)*number of replenishment intervals/hr (4 intervals/hr)*(1-(1-saliva extraction factor (0.5)^(number of hand-to-mouth contact events per hour (13.9 events/hr); *Hand Residue Loading* = (fraction of ai on hands compared to total surface residue from dermal TC study (0.06)*dermal exposure (mg))/typical surface area of one hand (150 cm^2).
2. **Object-to-Mouth =** ((Object Residue (µg/cm^2)*CF1 (1.0E-3 mg/µg)*Object Surface Area Mouthed/Event (10 cm^2/event))*(Exposure Time (1.5 hrs/day)*#Replenishment Intervals/hr (4))*(1-((1-Extraction by Saliva (0.48))^(#Object-to-Mouth Events/hr (8.8 events/hr)/#Replenishment intervals/hr))))/Body Weight (11kg).
3. **Soil Ingestion =** (Soil Residue (7.0746975 µg/g) *Ingestion Rate (50 mg/kg/day) *CF(0.000001))/Body Weight (11 kg).
4. **MOE** = NOAEL/Daily Dose (mg ai/kg/day); Oral NOAEL = 50 mg/kg/day.

5.1 Spray Drift

Spray drift is always a potential source of exposure to residents nearby to spraying operations. This is particularly the case with aerial application, but, to a lesser extent, could also be a potential source of exposure from the ground application method employed for fludioxonil. The Agency has been working with the Spray Drift Task Force, EPA Regional Offices and State Lead Agencies for pesticide regulation and other parties to develop the best spray drift management practices (see the Agency's Spray Drift website for more information[2]. The Agency has completed its evaluation of the new database submitted by the Spray Drift Task Force, a membership of U.S. pesticide registrants, and is developing a policy on how to appropriately apply the data and the AgDRIFT computer model to its risk assessments for

[2] Available: http://www.epa.gov/opp00001/factsheets/spraydrift.htm

pesticides applied by air, orchard airblast and ground hydraulic methods. After the policy is in place, the Agency may impose further refinements in spray drift management practices to reduce off-target drift with specific products with significant risk estimates associated with drift.

5.2 Residential Bystander Post-application Inhalation

Based on the Agency's current practices, a quantitative post-application inhalation exposure assessment was not performed for fludioxonil at this time. However, volatilization of pesticides may be a source of post-application inhalation exposure to individuals nearby pesticide applications. The Agency sought expert advice and input on issues related to volatilization of pesticides from its Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (SAP) in December 2009, and received the SAP's final report on March 2, 2010 (http://www.epa.gov/scipoly/SAP/meetings/2009/120109meeting.html). The Agency is in the process of evaluating the SAP report and may, as appropriate, develop policies and procedures to identify the need for and, subsequently, the way to incorporate post-application inhalation exposure into the Agency's risk assessments. If new policies or procedures are developed, the Agency may revisit the need for a quantitative post-application inhalation exposure assessment for fludioxonil.

5.3 Combined Residential Risk Estimates (Multiple Exposure Scenarios)

Because the exposure to treated ornamentals/gardens and turf could be expected within the same day, the handler application exposure from treated ornamentals/gardens and turf were combined (Table 5.3). Both the ornamental/garden and turf use is on the same label Medallion®II.

5.4 Residential Risk Estimates for Use in Aggregate Assessments

Table 5.4 reflects the residential risk estimates that are recommended for use in the aggregate assessment for fludioxonil.

- The recommended residential exposure for use in the adult aggregate assessment reflects inhalation exposure from mixing/loading/applying a wettable powder in water-soluble packaging with hose end sprayer (both for turf and gardens).
- The recommended residential exposure for use in the children 1<2 years old aggregate assessment reflects incidental oral exposures (hand-to-mouth) from post-application exposure to outdoor treated turf.

Table 5.3. Residential Combined (Multiple Exposure Scenarios) Non-Cancer Exposure and Risk Estimates for [Fludioxonil.						
Combined Exposure Scenario	**Lifestage**	**Exposure Scenario**	**Route of Exposure**	**Dose (mg/kg/day)[1]**	**Combined Total Dose (mg/kg/day)[2]**	**Combined Total MOEs[3]**
Outdoor Scenario (Turf/Garden)	Adult	Handler: Turf - Sprays	Inhalation	1.4E-04	0.00062	81,000
		Handler: Garden - Sprays	Inhalation	0.00048		

1 Dose (mg/kg/day) taken from Table 5.1.
2 Combined Total Dose (mg/kg/day) = combined inhalation doses for handlers ..
3 Combined Total MOEs = 1 ÷ (1/inhalation MOE) for handlers

Table 5.4. Recommendations for the Residential Exposures for the Fludioxonil Short-term Aggregate Assessment.									
Lifestage	Exposure Scenario	Dose (mg/kg/day)[1]				MOE[2]			
		Dermal	Inhalation	Oral	Total	Dermal	Inhalation	Oral	Total
Adult Male	Handler: Treating Turf and Gardens/Trees	N/A	**0.00062**	N/A	**0.00062**	N/A	**81,000**	N/A	**81,000**
Child	Post-application: Hand-to-Mouth from Treated Turf	N/A	N/A	**0.0101**	**0.0101**	N/A	N/A	**4,800**	**4,800**

1 Dose = the highest dose for each applicable lifestage of all residential scenarios assessed. Total = dermal + inhalation + incidental oral (where applicable).
2 MOE = the MOEs associated with the highest residential doses. Total = 1 ÷ (1/Dermal MOE) + (1/Inhalation MOE) + (1/Incidental Oral MOE), where applicable.

6.0 Occupational Exposure and Risk Estimates

Based on the proposed use, exposure is possible for individuals that handle the end-use product, and for individuals that may enter the treatment area (in this case, a packing house room). The proposed use is a very specific use pattern (thermal fogger). Data for this specific exposure scenario are not available to HED. Therefore, surrogate data were used (see below). HED conducted a conservative assessment of short- and intermediate-term risks to handlers. Post-application dermal exposure was not quantitatively assessed since there is no dermal POD, and post-application inhalation exposure is expected to be negligible due to personal protective equipment (PPE) required on Scholar® EZ label, as well as requirements on the proposed label that no entry into the treated room be allowed for 8 hours if there is no ventilation followed by one hour of mechanical ventilation, or for 24 hours with no ventilation.

6.1 Occupational Handler Exposure/ Risk Estimates

A thermal fogger is an automatic fogging machine which is located outside the area where the harvested pome fruit is stored and treated. The fog, which contains fludioxonil, is piped into the storage room, which is typically sealed tightly for climate control. The material is transferred from the product container into the fogging machine by pipe. The machine then slowly draws the solution out of the tank, heats it up to convert it to fog, and sends the fog into the storage room through a pipe. The fog is not released in the presence of the handler. Therefore, the only significant source of exposure is during the pouring of the end-use product into the fogging machine tank. This exposure was assessed as a mixer/loader scenario using PHED (open mixing loading of wettable powder).

A separate applicator assessment was not conducted. Since the application of fludioxonil is mechanically automated for the thermal fogging machine. A mixer/loader assessment was performed and is considered to result in a conservative estimate of worker risk. There are no risk estimates that are of concern.

Application Rate: The application rate is the maximum rate identified on the proposed Scholar® EZ label. The maximum application rate for treatment of pome fruit using a thermal fogger is 3.6 ounces or 0.2205 pounds of fludioxonil per 90,000 lb of fruit or 0.0000024 lb ai per lb of fruit.

Unit Exposures (UE): It is the policy of HED to use the best available data to assess handler exposure. Sources of generic handler data, used as surrogate data in the absence of chemical-specific data, include the PHED 1.1, the AHETF database, the ORETF database, or other registrant-submitted occupational exposure studies. Some of these data are proprietary and subject to the data protection provisions of FIFRA. The standard values recommended for use in predicting handler exposure that are used in this assessment, known as “unit exposures”, are outlined in the “Occupational Pesticide Handler Unit Exposure Surrogate Reference Table” (http://www.epa.gov/opp00001/science/handler-exposure-table.pdf), which, along with additional information on HED policy on use of surrogate data, including descriptions of the various sources, can be found at http://www.epa.gov/pesticides/science/handler-exposure-data.html.

Amount Treated: Information on amount of fruit treated per day was taken from e-mail correspondence from Bill Chism, BEAD, USEPA on December 13, 2013. For this assessment, it was assumed that a maximum of 6,712,960 lbs of pome fruit is treated per day. This amount is based on the following assumptions:

- In the US, apples are the most common of pome fruit.
- In the 2007 Census of Agriculture, Washington State was the greatest producer of apples (http://www.agcensus.usda.gov/Publications/2007/Full_Report/Volume_1,_Chapter_2_US_State_Level/st99_2_032_032.pdf).
- In warehouses, there are approximately 40.02 pounds of apples per cubic foot (http://www.aqua-calc.com/page/density-table/substance/Apples).
- The fog technology was initially developed to prevent scald (w/diphenyl amine), although it is combined with fungicides now for post-harvest rot control. It is assumed to be applied to full controlled atmosphere (CA) storage facilities (chamber treatment). The mist can expand to every corner of the storage chamber and adheres to the fruit. The large, airtight CA rooms in the state of Washington vary in size from 10,000 boxes to 100,000 boxes, depending on the volume of apples produced by the apple shipper and the marketing strategies (http://www.bestapples.com/facts/facts_controlled.aspx). A single box of apples has a 2,900 cubic inch capacity (United States Standards for Grades of Apples http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5050339)

Estimated controlled atmosphere minimum chamber sizes

Volume of single apple box (cubic inches)	Conversion factor (cu inches in a cu ft)	Volume of single apple box (cubic ft)	Volume of 10,000 box chamber (cu ft)	Volume of 100,000 box chamber (cu ft)
2,900	1,728	1.678241	16,782	167,824

Note: The chambers will be somewhat larger to allow for air flow and movement of forklifts.

This would result in a range of **671,615**(16,782 cu ft * 40.02 lbs apples/cu ft) **and 6,716,316** (167,824 cu ft * 40.02 apples/cu ft) **lbs of apples** depending on the size of the box chamber.

Body Weight (BW): The average body weight of an adult (80 kg) was used for all risk assessments.

Equations/Calculations: The following equations were used to calculate handler exposure and risk:

Exposure (mg/kg/day) = Rate (lb ai/lb fruit) x UE (mg /lb ai) x Amount Treated (lbs/day) / BW (kg)

Where:

Rate	=	Maximum application rate on product label (lb ai/lb fruit);
UE	=	Unit Exposure (µg ai/lb ai);
Amount Treated	=	Maximum amount treated per day (lb fruit/day); and
BW	=	Body weight (80 kg).

Total MOE (for Inhalation Risk) = NOAEL (mg/kg/day) / Exposure (mg/kg/day)

The mixer/loader inhalation exposure scenarios resulting from thermal fogging of pome fruit are presented below in Table 6.1. There are no short- or intermediate-term occupational risk estimates of concern associated with the proposed new use of fludioxonil.

Table 6.1 Short and Intermediate-Term Occupational Handler Non-Cancer Exposure and Risk Estimates for Fludioxonil

Exposure Scenario	Crop or Target	Short- and Intermediate term-Inhalation Unit Exposure (µg/lb ai)	Application rate (lb ai/lb fruit)[a]	Amount Treated Daily (lb fruit/day)[b]	Doses (mg/kg/day)[c]	MOEs[d]
					Short- and intermediate-term	Short-and intermediate -term
Mixer/Loading						
Mixing/loading wettable powder formulation	Pome Fruit	Baseline[e]: 43.4	0.0000024	671,615	Inhalation Baseline: 0.000866	Inhalation Baseline: 58,000
				6,716,316	Inhalation Baseline: 0.00866	Inhalation Baseline: 5,800

a Application rate is the maximum recommended rates provided on the proposed Scholar® EZ label .
b Amount treated per day value is based on an December 13, 2013 e-mail from Bill Chism, BEAD/EPA.
c Dose (mg/kg/day) = Unit exposure (mg/lb ai) x App Rate (lb ai/lb fruit) x Amount Treated (lb fruit/day) x %Absorption (100% inhalation assumed) / Body weight (80 kg).
d MOE = NOAEL/Dose; where the short- and intermediate-term inhalation (NOAEL = 50 mg/kg/day)
e Baseline Inhalation: no respirator.

6.2 Occupational Post-application Exposures / Risk Estimates

Post-application dermal exposure was not quantitatively assessed since there is no dermal POD, and post-application inhalation exposure is expected to be negligible due to personal protective equipment (PPE) required on Scholar® EZ label, as well as requirements on the proposed label that no entry into the treated room be allowed for 8 hours if there is no ventilation followed by one hour of mechanical ventilation, or for 24 hours with no ventilation.

Appendix A. Summary of Occupational Non-cancer Algorithms

Occupational Non-cancer Handler Algorithms

Potential daily exposures for occupational handlers are calculated using the following formulas:

where:

E	=	exposure (mg ai/day),
UE	=	unit exposure (µg ai/lb ai),
AR	=	maximum application rate according to proposed label (lb ai A or lb ai/gal), and
A	=	area treated or amount handled (e.g., A/day, gal/day).

The daily doses are calculated using the following formula:

$$\frac{\qquad}{\qquad}$$

where:

ADD	=	average daily dose absorbed in a given scenario (mg ai/kg/day),
E	=	exposure (mg ai/day),
AF	=	absorption factor (dermal and/or inhalation), and
BW	=	body weight (kg).

Margin of Exposure: Non-cancer risk estimates for each application handler scenario are calculated using a Margin of Exposure (MOE), which is a ratio of the toxicological endpoint to the daily dose of concern. The daily dermal and inhalation dose received by occupational handlers are compared to the appropriate POD (i.e., NOAEL) to assess the risk to occupational handlers for each exposure route. All MOE values are calculated using the following formula:

$$\frac{\qquad}{\qquad}$$

where:

MOE	=	margin of exposure: value used by HED to represent risk estimates (unitless),
POD	=	point of departure (mg/kg/day), and
ADD	=	average daily dose absorbed in a given scenario (mg ai/kg/day).